

Amendment #1
RFP NIH-NIAMS-BAA-05-02
PILOT AND FEASIBILITY TRIALS FOR OSTEOPOROSIS

Amendment to Solicitation No.: NIH-NIAMS-05-02

Amendment No.: 1

Amendment Date: February 1, 2005

RFP Issue Date: January 14, 2005

Issued By: Chief Contracting Officer
Contracts Management Branch
National Institute of Arthritis and Musculoskeletal
and Skin Diseases, National Institutes of Health
One Democracy Plaza, Suite 800, MSC 4872
6701 Democracy Boulevard
Bethesda, MD 20892-4872

Point of Contact: Eileen Webster-Cissel

Name and Address of Contractor: N/A

The above numbered solicitation is amended as set forth below.

The hour and the date specified for receipt of offers IS NOT EXTENDED.

Offerors must acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by one of the following methods:

1. By acknowledging receipt of this amendment on each copy of the offer submitted; or
2. By separate letter, telegram, or Electronic Mail to Mr. Dean Guidi (guidid@mail.nih.gov) which includes a reference to the solicitation and amendment numbers.
3. By requesting a copy of the Standard Form 30 for this amendment and completing the information requested in items 8 and 15, and returning 1 copy of the amendment; (a hard copy of this amendment, including the Standard Form 30, may be requested from Mr. Dean Guidi (guidid@mail.nih.gov)).

FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.

RFP NIH-NIAMS-BAA-05-02 is hereby amended as follows:

PART II – CONTRACT CLAUSES, SECTION I – CONTRACT CLAUSES, ARTICLE I.3., ADDITIONAL CONTRACT CLAUSES, is hereby amended to delete FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (JUNE 2003).

PART III - LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS, SECTION J – LIST OF ATTACHMENTS, is hereby amended to read as follows:

SECTION J - LIST OF ATTACHMENTS

The following documents or exhibits are either attached or are available on line at <http://www.niaid.nih.gov/contract/ref.htm> and are incorporated into this RFP:

THE FOLLOWING FORM MUST BE COMPLETED AND SUBMITTED PRIOR TO THE SUBMISSION OF YOUR PROPOSAL:

1. Attachment 1 - Proposal Intent Response Sheet, 1 page (attached).

THE FOLLOWING FORMS MUST BE COMPLETED AND SUBMITTED WITH EACH TECHNICAL PROPOSAL: (A copy of each form shall be included with the original and every copy of the technical proposal, these documents are available at:

<http://www.niaid.nih.gov/contract/ref.htm>).

2. Government Notice for Handling Proposals
3. Technical Proposal Cost Summary
4. Summary of Related Activities,
5. Targeted/Planned Enrollment Table, 01 (Mod. By OAMP 10/2001),
6. Protection of Human Subjects Assurance Identification/IRB Certification/Declaration, OMB No. 0990-0263 (formerly Optional Form 310).

THE FOLLOWING FORMS MUST BE COMPLETED AND SUBMITTED WITH EACH BUSINESS PROPOSAL (available on-line at <http://www.niaid.nih.gov/contract/ref.htm>):

7. NIH-2043, Proposal Summary and Data Record.
8. Breakdown of Proposed Estimated Cost (Plus Fee).
9. SF-LLL, Disclosure of Lobbying Activities.
10. Small Business Subcontracting Plan Format. (only if requested by C.O., see Section L.1.c, page 17, "Just in Time")
11. Small Disadvantaged Business (SDB) Participation Plan.
12. Offeror's Points of Contact.

THE FOLLOWING FORMS WILL BE ATTACHED TO ANY CONTRACT RESULTING FROM THIS RFP:

13. NIH (RC)-7, Procurement of Certain Equipment, (OMB Bulletin 81-16).
14. NIH (RC)-4, Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts.
15. NIH (RC)-11, Research Patient Care Costs.
16. NIH 2706, Financial Report of Individual Project/Contract, with instructions.
17. Safety and Health, HHSAR Clause 352.223-70.
18. Inclusion Enrollment Report.
19. Privacy Act Systems Notice, April 1997, 10 pages (Attachment 2 to this RFP)

SECTION IV, REPRESENTATIONS AND INSTRUCTIONS, is hereby modified as follows:

SECTION L.2, INSTRUCTIONS TO OFFERORS, paragraph a, General Instructions, paragraph 9, Standards for Privacy of Individually Identifiable Health Information, second paragraph, is hereby amended to correct the web site links:

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (<http://www.hhs.gov/ocr/>) provides information about the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements, and contracts can be found at: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

SECTION L.2, INSTRUCTIONS TO OFFERORS, paragraph a, General Instructions, paragraph 12, Small Business Subcontracting Plan, subparagraph c) is hereby amended and should read as follows:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer; the negotiated plan will be incorporated into the contract, as a material part thereof.

SECTION L.2, INSTRUCTIONS TO OFFERORS, paragraph a, General Instructions, paragraph 21, Sharing Research Data is hereby amended to correct the web site link in the paragraph:

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:
<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

SECTION L.2, INSTRUCTIONS TO OFFERORS, paragraph b, Technical Proposal Instructions, paragraph 6, Human Subjects, the NOTE following subparagraph f), is hereby amended to correct the web site links, and to read as follows:

**Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at <http://www.hhs.gov/ohrp/>. Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html*

SECTION L.2, INSTRUCTIONS TO OFFERORS, paragraph b, Technical Proposal Instructions, paragraph 8, Required Education in the Protection of Human Research Participants, second paragraph is amended to correct the web site links:

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at <http://ohsr.od.nih.gov/cbt/cbt.html>. This site may be downloaded at no cost and modified for the use by the offeror, if desired. In addition, the University of Rochester has made available its training program for individual investigators, and completion of this program will satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_prof_protect.html. If an institution has already developed educational programs on the protection of research participants, completion of these programs will also satisfy the educational requirement.

SECTION L.2, INSTRUCTIONS TO OFFERORS, paragraph b, Technical Proposal Instructions, paragraph 13, Research Involving Prisoners as Subjects, is amended to correct the web site links:

(13) Research Involving Prisoners as Subjects

- a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS-funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: <http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.pdf>
- b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological

research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:
 - a) to describe the prevalence or incidence of a disease by identifying all cases, or
 - b) to study potential risk factor associations for a disease, and
2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2-7) and determined and documented that:
 - a) the research presents no more than minimal risk, and
 - b) no more than inconvenience to the prisoner-subjects, and
 - c) prisoners are not a particular focus of the research.

For more information about this Waiver see

<http://www.hhs.gov/ohrp/special/prisoners/Prisoner%20waiver%206-20-03.pdf>.

SECTION L.2, INSTRUCTIONS TO OFFERORS, paragraph b, Technical Proposal Instructions, paragraph 15, Human Embryonic Germ Cell (HEGC) Research, is amended to correct the web site links:

1. Guidelines.

Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (<http://stemcells.nih.gov/news/newsArchives/fr25au00-136.asp>) and (<http://stemcells.nih.gov/news/newsArchives/fr14no01-95.asp>) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See NIH Guide for Grants and Contracts Notice NOT-OD-02-049, requiring that offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group (HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

All offerors should read the "NIH Guidelines:"

(<http://stemcells.nih.gov/news/newsArchives/fr25au00-136.asp>) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2) are responding to a Statement of Work that requires the use of human embryonic germ cells.

Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

2. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If, in response to the solicitation, the offeror proposes to use human embryonic germ cells, it must submit, as a separate attachment to its proposal, an original and two copies of the documentation and assurances that address the areas covered in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html>). Prior to any award made under this solicitation, the documentation and assurances will be subject to review by the HPSCRG, which meets in a public meeting. No research involving the use of human embryonic germ cells may begin prior to HPSCRG approval.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b. of the NIH Guidelines. Offerors should also review the April 10, 2002, DHHS Office of Human Research Protection's document titled "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles," <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-044.html>)